

REMARKS

Applicants have carefully reviewed the Final Office Action mailed March 3, 2003, in which pending claims 1, 2 and 4-21 were rejected.

Claim Rejections—35 U.S.C. § 102

Claims 1, 2, 8 and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Truckai (U.S. Patent No. 5,019,057). Applicant respectfully disagrees.

The Examiner asserts that the steel wire of Truckai meets the claim limitation of claim 1 of “a second highly radiopaque metal wire”. This is done by saying that since stainless steel is more radiopaque than some materials, it is highly radiopaque. The definition applied by the Examiner is broader than the broadest reasonable interpretation and ignores the claim language. Moreover, this definition is not consistent with the interpretation that those skilled in the art would reach.

The undue breadth of the definition adopted by the Examiner can be illustrated by applying the same logical structure to the definition of slightly radiopaque. To wit: since stainless steel is less radiopaque than some materials, such as gold, it is considered to meet the limitation of slightly radiopaque. Stainless steel, by this logic, is both highly and slightly radiopaque, which cannot be if the words “highly” and “slightly” are to have any meaning at all. The logic used completely eviscerates the meaning of the word “highly” and produces a definition that is broader than the broadest reasonable definition.

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999). The definition of “highly” as modifying radiopaque put

forward by the Examiner is inconsistent with the interpretation that those skilled in the art would reach. The references provided by the examiner are inapposite.

For instance, the Samson reference reads in pertinent part, “The metal band may be of gold, platinum, platinum-tungsten alloy, stainless steel, or other suitable and, preferably, radioopaque [sic] materials.” This reference, by its language “preferably”, does not require suitable materials to be radiopaque and also does not contain language that equates the levels of radiopacity of any of the listed materials. A reasonable interpretation is that the listed materials have a level of radiopacity suitable for the particular embodiments of Samson. Asserting that Samson equates the level of radiopacity of the materials listed or that it regards any or all of the materials to be highly radiopaque is not supported by the language.

Likewise, the Krütten reference merely points out that steel is radiopaque, not highly radiopaque. Krütten does not discuss the degree of radiopacity; it merely points out that the radiopacity of steel is suitable for the particular embodiments of Krütten. It is notable that Krütten requires the strips to be of conduction material in some embodiments, which limits the material selection. See column 1, lines 54-57. Applicants are not disagreeing that steel has a degree of radiopacity and that degree of radiopacity is suitable in certain applications; Applicants are asserting that steel does not have a high degree of radiopacity.

The Devon Medical reference says nothing about the inherent radiopacity of stainless steel. The Examiner points out that the PURA-VARIO line of stents on page 2, made from 316L stainless steel, is described as having “very good” radiopacity. The reference also describes a two other lines of stents made from the same 316L stainless steel, the PURA-VARIO-AS and the PURA-VARIO-AL, as having “moderate” radiopacity. The reference, therefore, cannot support the proposition that steel has the inherent property of high radiopacity. The characterization in

the reference of the radiopacity of the several lines of stents must be in reference to the context of their use, e.g., the PURA-VARIO stent has “very good” radiopacity for its application. The Devon Medical reference cannot mean that steel is inherently both a moderately radiopaque material and a highly radiopaque material, nor can the reference support either proposition separately.

The references cited by the examiner, therefore, do not support the proposition that steel is highly radiopaque.

A survey of references, both of patents and of publications available over the Internet, suggests that characterizing stainless steel as “highly radiopaque” is not consistent with the interpretation that those skilled in the art would reach, as required by case law. See *In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999).

For instance, Olsen et al. (Patent No. 6,245,068) note that “the radiopacity of stainless steel is, however, relatively low.” Column 2, lines 14-15.

Likewise, Viera (U.S. Patent No. 5,353,808) relies on the low radiopacity of stainless steel in its embodiments. Viera states that “one problem with currently available guidewires concerns the visibility of the guidewire. If the guidewire is fully opaque on a viewing screen, it can hinder viewing of post angioplasty angiograms...” Column 1, lines 45-48. An embodiment described in Viera is a guidewire 10 that includes a center stainless steel core 40 and bands or regions 30 of high radiopaqueness. See column 3, lines 18-33. This embodiment is noted as having solved the above problem by allowing “adequate tracing of the guidewire while minimizing interference with a post procedure angiogram” and is noted as not being fully radiopaque (even though it has a stainless steel core wire). Column 3, lines 25-28 and column 4, lines 49-50.

In the Cathguide reference on page 1, subheading *Materials*, the author notes that stainless steel wires do not have radiopacity comparable to precious metal wires.

The authors note in “Gold Coated NIR Stents in Porcine Coronary Arteries” that “Radiopacity in particular is poor with stainless steel and worse when struts are made thinner or spaced farther apart”. (Page 429, first paragraph.)

On page S18, second and third column of “Stent Design: Implications for Restenosis”, the authors both characterize and compare 316L stainless steel to cobalt chromium alloys. Notably absent from the list of advantages of 316L stainless steel (easy to work with, good mechanical properties, and hemocompatibility) is a high degree of radiopacity. Cobalt chromium alloys, in comparison to stainless steel alloys, “may allow the routine manufacture of thinner, more radiopaque stents that cause less distortion on a magnetic resonance imaging (MRI) scan.” Thus, cobalt chromium alloys are so much more radiopaque than stainless steel that less of the material is needed to create more radiopaque stents.

In the Outlook reference on page 10, subtitle *Radiopacity*, the author discusses the radiopacity of steel:

Nitinol produces a fluoroscopic image which is comparable to that of stainless steel, if the mass and dimensions of the parts examined are similar. Although this degree of radiopacity is sufficient in many cases, an improvement would be beneficial. While stainless steel can be gold-coated, for example, with sufficient thickness to enhance radiopacity, layers of gold and other radiopaque materials might negatively influence the superelastic performance of Nitinol.

Applicant submits that these references show a fair summary of what those of skill in the art think of the radiopacity of stainless steel. Those of skill in the art characterize stainless steel as “low” or “poor”, and sufficient for some purpose and insufficient for other purposes. A

definition of highly radiopaque metals that includes stainless steel would, therefore, be inconsistent with the interpretation that those of skill in the art would reach.

Applicant submits that Truckai does not anticipate the invention of claims 1-2 and 8-9 because Truckai does not include a wire made from a highly radiopaque metal. Applicant thus submits that these claims are in condition for allowance.

Claim Rejections 35 U.S.C. § 103

Claims 1, 2 and 4-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sater et al. (U.S. Patent No. 6,068,622) in view of Truckai. Applicant respectfully disagrees.

As neither Sater et al. nor Truckai disclose a highly radiopaque metal wire, the claimed invention of claim 1 is non-obvious in view of these references. As claims 2 and 4-18 depend from claim 1 and contain additional distinguishing elements, Applicants submits that these claims are in condition for allowance as well.

Claims 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Truckai in view of Chien et al. (U.S. Patent No. 6,165,163). Claim 21 was rejected as being unpatentable over Truckai in view of Sater et al. and further in view of Chien. Applicant respectfully disagrees.

As these claims depend, directly or indirectly, from claim 1, which Applicant submits is patentable, and contain additional distinguishing elements, applicants submit that these claims are also in condition for allowance.

Information Disclosure Statement

Applicant notes that the Examiner has not acknowledged consideration of the IDS submitted with the response mailed on December 12, 2002. Applicant requests a copy of the PTO-1449 checked off and returned with the next communication from the Examiner.

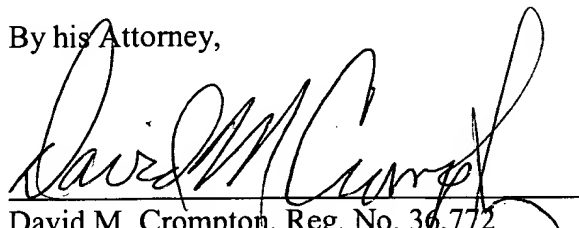
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims, namely claims 1, 2 and 4-21, are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Henry J. Pepin

By his Attorney,

Date: 5/2/03


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